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APPARATUS FOR IMPLANTING DEVICES  
IN ATRIAL APPENDAGES

5 This application claims the benefit of U.S.  
provisional application No. 60/234,111, filed September  
21, 2000, which is hereby incorporated by reference in  
its entirety herein.

Background of the Invention

Field of the Invention

10 The invention relates to apparatus for  
implanting devices in atrial appendages. The devices  
may be used to filter or otherwise modify blood flow  
between the atrial appendage and an associated atrium  
of the heart to prevent thrombi from escaping from the  
15 atrial appendage into the body's blood circulation  
system. In particular the invention relates to  
apparatus for percutaneous delivery and implantation of  
such devices.

Description of the Related Art

20 There are a number of heart diseases (e.g.,  
coronary artery disease, mitral valve disease) that  
have various adverse effects on a patient's heart. An  
adverse effect of certain cardiac diseases, such as  
mitral valve disease, is atrial (or auricular)

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fibrillation. Atrial fibrillation leads to depressed cardiac output. A high incidence of thromboembolic (i.e., blood clot particulate) phenomena is associated with atrial fibrillation, and the left atrial appendage (LAA) is frequently the source of the emboli (particulates).

Thrombi (i.e., blood clots) formation in the LAA may be due to stasis within the fibrillating and inadequately emptying LAA. Blood pooling in the atrial appendage is conducive to the formation of blood clots. Blood clots may accumulate and build upon themselves. Small or large fragments of the blood clots may break off and propagate out from the atrial appendage into the atrium. The blood clot fragments can then enter the body's blood circulation and embolize distally into the blood stream.

Serious medical problems result from the migration of blood clot fragments from the atrial appendage into the body's blood stream. Blood from the left atrium and ventricle circulates to the heart muscle, the brain, and other body organs, supplying them with necessary oxygen and other nutrients. Emboli generated by blood clots formed in the left atrial appendage may block the arteries through which blood flows to a body organ. The blockage deprives the organ tissues of their normal blood flow and oxygen supply (ischemia), and depending on the body organ involved leads to ischemic events such as heart attacks (heart muscle ischemia) and strokes (brain tissue ischemia).

It is therefore important to treat cardiac conditions to prevent fragments or emboli generated by any blood clots that may have formed in the atrial appendages, from propagating through the blood stream to the heart muscle, brain or other body organs.

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Some recently proposed methods of treatment are directed toward implanting a plug-type device in an atrial appendage to occlude the flow of blood therefrom.

5 A preventive treatment method for avoiding thromboembolic events (e.g., heart attacks, strokes, and other ischemic events) involves filtering out harmful emboli from the blood flowing out of atrial appendages. Co-pending and co-owned U.S.  
10 patent application No. 09/428,008, U.S.  
patent application No. 09/614,091, U.S.  
patent application No. 09/642,291, U.S.  
patent application No. 09/697,628, and U.S.  
patent application No. 09/932,512, all of which are  
15 hereby incorporated by reference in their entireties herein, describe expandable filtering devices which may be implanted in an atrial appendage to filter the blood flow therefrom.

The implant devices in a compact state may be  
20 delivered to their atrial appendage situs percutaneously through femoral or jugular blood vessels using conventional catheterization apparatus. The position of an implanted device may be observed using common imaging techniques, for example, radiography or  
25 echocardiography. The implant devices are deployed by expanding them in situ. The devices are retained in position by expandable structures which engage surrounding atrial appendage tissue. The expandable structures may include tissue piercing anchors.

30 To function effectively the devices must be deployed from suitable positions within or about the atrial appendages. For example, the filter elements of a device must be correctly centered or positioned across an atrial appendage ostium for the device to

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properly intercept and filter blood flowing out of the atrial appendage. Placing a device in a suitable deployment position may require position probing or adjustment from an initial as-delivered position.

5           It would therefore be desirable to provide catheterization apparatus having positioning guides, which enable controlled position probing and readjustment of the initial as-delivered implant device position to place the device in a suitable deployment  
10 position in the atrial appendage.

Further, the implant procedures may include transseptal catheterization which involves puncturing an atrial septum and advancing an access sheath through the septum. The access sheath provides a conduit  
15 through which an implant device may be delivered across the septum into the adjoining atrium. Inadvertent movement of the sheath during the catheterization procedure may lead to undesirable medical complications. For example, retrograde slippage may  
20 cause the sheath to disengage from the septum, which in turn may necessitate repeated puncturing or crossing of the septum to regain access to the adjoining atrium. Further, instability in the position or orientation of the access sheath may make the delivery of a device for  
25 placement in an appendage geometrically difficult.

It would therefore also be desirable to provide transseptal catheterization apparatuses which include securement devices for restraining the movement of and securing the position of the access sheath  
30 traversing the septum.

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Summary of the Invention

10 5 The invention provides a catheterization apparatus having a positioning device or guide, which enables controlled position probing and readjustment of the initial as-delivered implant device position. The catheterization apparatus may include one or more nested tubes, wires or shafts. The positioning guide may be attached to a positioning tube passing through the catheter apparatus. Using the positioning guide, 10 the implant device position in the atrial appendage may be readjusted from the as-delivered position to a desired deployment position.

15 The positioning guide may have an expandable structure. The structure may be expandable from a compact state to an expanded state. The positioning guide is delivered in its compact state to a location adjoining the ostium of an atrial appendage. The apparatus may include size-adjusting mechanisms for expanding the positioning guide in situ. The 20 positioning guide may be deployed by expanding it to engage or contact portions of the atrial wall proximate to the ostium for mechanical support. The deployed guide thereby holds and stabilizes outer portions of the catheter apparatus in a fixed position. An implant 25 device attached to a shaft passing through the catheterization apparatus may then be reversibly positioned within the atrial appendage. The implant device position may be monitored, for example, by echocardiography, radiography or fluoroscopy. After 30 the implant device is suitably positioned and deployed, the positioning guide may be contracted to its compact non-expanded state and retracted.

In an embodiment of the catheterization apparatus which may be useful for transseptal

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catheterization, a securement means is attached to an access sheath in the catheterization apparatus. The access sheath is used to puncture an atrial septum and then advanced through the puncture to provide a passage way through which an implant device may be delivered to an adjoining atrium. The securing means may, for example, include an inflatable disk having an inflated diameter that is larger than the size of the septal puncture. The inflatable disk may be deployed to engage distal surfaces of the punctured septum to secure the position of the access sheath relative to the septum.

Other embodiments of the positioning guides (and securement means) may have other kinds of inflatable or expandable structures which allow the positioning devices (and securement means) to have compact sizes for delivery and which can later be enlarged in situ.

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawing and the following detailed description.

#### Brief Description of the Drawings

FIG. 1 is a partial cross sectional view of a heart illustrating a conventional catheter entering a left atrial appendage using a transseptal procedure.

FIGS. 2a and 2b illustrate examples of wire patterns or configurations of expanded positioning guides in accordance with the principles of the invention

FIG. 2c schematically illustrates an inflatable balloon-type positioning guide in accordance with the principles of the invention.

FIG. 3 is a schematic view of a portion of a transseptal catheterization apparatus having a positioning guide for reversible or adjustable placement of an implant device in an atrial appendage, and a securement means for restraining movement of a septum-traversing access sheath in accordance with the principles of the invention.

FIG. 4 is a schematic view of a portion of the transseptal catheterization apparatus of FIG. 3 illustrating the deployment of the securement means to restrain movement of a septum-traversing sheath in accordance with the principles of the invention.

FIG. 5 is a schematic view of a portion of the transseptal catheterization apparatus of FIG. 3 illustrating figuratively the deployment of the positioning guide to engage atrial wall surfaces proximate to the ostium of an atrial appendage in accordance with the principles of the invention.

#### Description of the Preferred Embodiments

Implant devices for filtering or otherwise modifying blood flow between an atrial appendage and its atrium may be attached to a catheter shaft and then be percutaneously delivered to the appendage through a blood vessel leading to the heart.

FIG. 1 illustrates, for example, catheter 21 inserted through a femoral vein (not shown) entering the right atrium of the heart through the inferior vena cava 18, and then passing into left atrium 11 through the fossa ovalis 19 or through the septum 29 before entering the left atrial appendage 13. Alternatively (not shown in FIG. 1), catheter 21 may enter the left ventricle 16 of the heart through the aorta 12, and then pass through mitral valve 17 to reach left atrial

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appendage 13. An implant device (not shown) attached to catheter 21 may be used to prevent thrombus 30 or emboli generated therefrom from migrating into atrium 11. The device may include materials having  
5 suitable properties (e.g., radio-opacity) that make it possible to monitor the in-vivo device position during and after the catheterization position using external imaging techniques such as radiography or fluoroscopy, echocardiography, and ultrasound.

10 The present invention provides a catheterization apparatus having a positioning device or guide, which enables controlled position probing and readjustment of an initial as-delivered implant device position. The implant device position in the atrial  
15 appendage may be readjusted from the as-delivered position to a desired deployment position. The catheterization apparatus may include one or more nested tubes, wires or shafts. The positioning guide may be attached to a positioning tube passing through  
20 the catheter apparatus.

The positioning guide may have an expandable or inflatable structure designed to engage (contact) atrial wall portions surrounding the ostium. The structure may be designed to be reversibly expandable  
25 from a compact state suitable for percutaneous delivery and withdrawal. Further, the positioning guide may be designed to engage surrounding atrial wall portions to provide a stable and reproducible pathway for movement of a device-carrying shaft in and out of the atrial  
30 appendage.

The positioning guide may be made of suitable biocompatible materials including metals and polymeric materials such as ePFTE (e.g., Gortex®), polyester (e.g., Dacron®), PTFE (e.g., Teflon®), stainless steel

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Positioning guides according to one embodiment may be formed from lengths of wires. The wires may be made of suitable elastic materials including shape memory alloy materials such as nitinol. There may be one or more wires or wire configurations which make up the positioning guide. In the compact state of the positioning guide that is suitable for percutaneous delivery, the wires may lie substantially along the positioning tube. The wires or wire configurations made, for example, from shape-memory alloy materials, may have preformed shapes. In the expanded state of the positioning guides, these wires may revert to their preformed shapes in which they may extend away from the positioning tube. The extended wires may have any suitable configuration for engaging the atrial wall portions. For example, the extended wires may have a straight spoke-like pattern or have more complex patterns such as overlapping arcuate patterns. FIG. 2a illustrates, for example, a spoke-like configuration of wires 510 in the expanded or deployed state of a positioning guide 500. Wires 510 extend radially outward away from positioning tube 520 on which guide 500 is disposed. Further, for example, FIG. 2b illustrates an overlapping arcuate pattern of wires 510 in the expanded or deployed state of positioning guide 550.

The catheterization apparatus may include  
30 suitable size-adjusting mechanisms that allow the  
positioning guide to be reversibly expanded in situ.  
For example, the apparatus may include a retractable  
sleeve which covers and holds the elastic or  
shape-memory alloy wires forming a positioning guide in

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a compact configuration along or in close proximity to the positioning tube. The positioning guide may be deployed by retracting the sleeve to allow the wires to expand or unfurl radially outward. The sleeve may be  
5 moved forward to reverse the expansion as needed to return the positioning guide to its compact state. Alternatively, the wires may be contained within the delivery tube, and attached, for example, to a sliding push rod that enables the wires to be retractably  
10 extended through small diameter openings or holes in the delivery tube walls.

The positioning guide in its non-expanded compact state is delivered to a location adjoining the ostium of an atrial appendage. - The positioning guide  
15 is deployed by expanding it to engage or contact portions of the atrial wall proximate to the ostium for mechanical support. The outermost engagement points may be separated by distances that are larger than the positioning tube diameter. Preferably, the separation  
20 distances are several times larger than the positioning tube diameter to obtain a support configuration having a wide geometry that favors mechanical stability. Additionally, the position guide may be suitably advanced forward to bear upon the atrial wall portions  
25 with a contact pressure adequate to generate frictional resistance to its lateral movement. Thus, the deployed positioning guide may mechanically hold and stabilize the positioning tube in a fixed position relative to the ostium. An implant device attached to a shaft  
30 passing through the positioning tube may then be reversibly placed at a location within the atrial appendage. The implant device position may be monitored, for example, by electrocardiographic, radiographic, or fluoroscopic imaging. After the

implant device is suitably positioned or deployed, the positioning guide may be contracted and retracted.

Other embodiments of the positioning guides may have other kinds of inflatable or expandable structures which allow the positioning guides to have compact sizes for delivery and which can later be enlarged in situ. For example, positioning guides according to one of these other embodiments may have inflatable balloon-type structures. The balloons may be made of suitable elastic membranes, for example, made of urethane or silicone material. FIG. 2c schematically illustrates, for example, a balloon-type structure 560 of a positioning guide 570.

An embodiment of a catheterization apparatus may be useful for transseptal catheterization. The apparatus of this embodiment has an access sheath which is used to provide a conduit or pathway for device delivery across a septum between adjoining atriums. The apparatus includes a securement means which may be used to restrain movement of the septum-traversing access sheath. The securement means is disposed on or about the distal end of the access sheath.

The access sheath may be an outermost tube of the catheterization apparatus. Known catheterization techniques may be used to have the access sheath penetrate and traverse a septum. A known technique, for example, uses a conventional dilator (obturator) device having a covered needle in its tip. The dilator is preloaded in the access sheath such that the dilator tip extends out of the distal end of the access sheath. The preloaded access sheath is advanced into an atrium through the body's vasculature. Next, the dilator needle is advanced through the dilator tip to puncture the atrial septum, following which the dilator itself

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is advanced to dilate the puncture opening. The access sheath is then advanced through the dilated puncture opening across the septum into the adjoining atrium. Finally, the dilator device is then withdrawn from the  
5 access sheath.

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The securement means in the catheterization apparatus of the present invention may be deployed to restrain further movement of the septum-traversing access sheath. The securing means may, for example,  
10 include an inflatable disk having an inflated diameter that is larger than that size of the septal puncture or the diameter of the access tube. Preferably, the inflated diameter is several times larger than the diameter of the access tube. In catheterization  
15 apparatus useful for procedures on adult hearts, the inflated diameter may, for example, be in the range of about 5 to 10 mm. The inflatable disk may be fabricated from membranes made of biocompatible materials such as silicone, urethane, or other  
20 biocompatible polymers.

The catheterization apparatus may include suitable means for reversibly inflating the securement means. For example, the access sheath may include a tube connected to the inflatable disk structure through  
25 which pressurizing fluids may be supplied to inflate the disk. The inflatable disk may be deployed to engage the distal surfaces of the punctured septum to secure the position of the access sheath relative to the septum and to restrain inadvertent movement of the  
30 access sheath.

Other embodiments of the securement means may have other kinds of inflatable or expandable structures which allow the securement means to have compact sizes for delivery and which can later be enlarged in situ.

FIG. 2 illustrates, for example, transseptal catheterization apparatus 200 having a positioning guide 220 for reversible placement of an implant device 210 in an atrial appendage, and a securement means 230 for restraining inadvertent or uncontrolled movement of a septum-traversing access sheath 240.

Apparatus 200 includes coaxially nested access sheath 240, delivery tube 260, positioning tube 270, and device shaft 280, all of which are connected to or pass through handle manifold 250.

Access sheath 240 may form an outer tubular structure of catheterization apparatus 200. Rigid biocompatible tube materials such as metals and plastics may be used to fabricate access sheath 240. However, access sheath 240 may be sufficiently flexible for it to course through blood vessels leading to the heart. Access sheath 240 may have an outer diameter suitable for percutaneous passage to the heart through readily accessible blood vessels, for example, the femoral veins.

One end (proximal end) of access sheath 240 is attached to handle manifold 250. Inflatable securement means 230 is disposed on or built into access sheath 200 toward its distal end. Securement means 230 may be reversibly inflated, for example, by pressurizing fluids injected through inflation port 254 disposed on manifold 250.

Handle manifold 250 includes fluid seal structure 252 through which a delivery tube 260 passes through and retractably extends into access sheath 240. Fluid seal 252 may be any conventional seal designed to prevent leakage of fluids while delivery tube 260 is retracted or extended into access sheath 240. Fluid seal 252 may, for example, be a

conventional hemostatic seal. Rigid biocompatible tube materials such as metals and plastics similar to those used to fabricate access sheath 240 also may be used to fabricate delivery tube 260. Delivery tube 260 may have sufficient flexibility for it to course through access sheath 240 in the latter's deployed position through blood vessels leading to the heart. Delivery tube 260 may have an outer diameter sized to allow its smooth movement within access sheath 240. The outer diameter of delivery tube 260 also may be sufficiently smaller than the inner diameter of access sheath 240 to allow pressurizing fluids to flow between securement means 230 and inflation port 254. Alternatively or additionally, the outer surface of delivery tube 260 may be grooved to provide flow channels for pressurizing fluids to flow between securement means 230 and inflation port 254.

The inner diameter of delivery tube 260 is sized to be sufficiently large to accept and allow passage of positioning guide 220 disposed on the distal end of a positioning tube 270. Rigid biocompatible tube materials such as metals and plastics similar to those used to fabricate access sheath 240 and delivery tube 260 also may be used to fabricate positioning tube 270. Positioning tube 270 may be sufficiently flexible for it to course through delivery tube 260 in the latter's deployed position through access sheath 240. Positioning tube 270 retractably extends into delivery tube 260 through seal 256 disposed on the proximal end of delivery tube 260. Seal 256 is designed to prevent fluid leakage, and may, for example, be of a type similar to fluid seal 252.

Positioning guide 220 disposed on the distal end of positioning tube 270 may have a compact state

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from which it may be reversibly expanded to an expanded state. FIG. 2 shows for purposes of illustration an exemplary positioning guide 220 in its expanded state. Expanded positioning guide 220 has a structural  
5 configuration with four extended fingers 222 suitable for engaging or contacting atrial walls for mechanical support to stabilize the position of positioning tube 270. The four extended fingers shown in FIG. 3 have a size which substantially larger than the diameter of  
10 delivery tube 260. However, it will be understood that positioning guide 220 is passable through delivery tube 260 only when the former is in its compact retracted state. Positioning tube 270 may include means such as a trip wire, a push rod, a retractable sleeve, or other  
15 suitable means to reversibly deploy positioning guide 220. Positioning tube 270 itself may, for example, serve as a push rod, in which case positioning guide 220 may be expanded or contracted by respectively advancing or retracting positioning tube 270 through  
20 delivery tube 260.

The inner diameter of positioning tube 270 is sized to be sufficiently large to accept and allow passage of compacted implant device 210 attached to one end of a device shaft 280. Implant device 210 may, for  
25 example, be any one of the self-expanding or inflatable filtering devices disclosed U.S. patent application No. 09/428,008, U.S. patent application No. 09/614,091, U.S. patent application No. 09/642,291, U.S. patent application No. 09/697,628, and U.S.  
30 patent application No. 09/932,512, incorporated by reference herein. Device shaft 280 may be a conventional catheter shaft having conventional fixtures for device attachment. Device shaft 280 may, for example, have a solid or tubular structure made of

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solid metals, metal braids, solid polymers, polymer  
braids, or any suitable combination thereof. Shaft 280  
may enclose other tubes or structures that may be  
required for device deployment. For example, device  
5 shaft 280 may include some lumen for supplying fluids  
for inflation of an expandable balloon in a balloon-  
inflatable type of device 210.

Catheterization apparatus 200 (or other  
embodiments thereof) may be used to controllably and  
10 adjustably place an implant device at a suitable  
deployment location within an atrial appendage.  
Position guide 220 and/or securement means 230 may be  
used to provide a mechanically stable pathway for  
delivery of the device, and for adjusting the device  
15 location within the atrial appendage before device  
deployment.

With reference to FIG. 4, in a transseptal  
catheterization procedure, access sheath 240 with  
securement means 230 in its compact state is introduced  
20 into a right atrium 330 through the body's vasculature.  
The progress of access sheath 240 through the body may  
be monitored, for example, by echocardiography,  
radiographic or fluoroscopic imaging. A conventional  
needle and dilator assembly (not shown) reversibly  
25 sliding through access sheath 240 may be used to  
puncture and dilate septum 310. Access sheath 240 is  
advanced forward through the dilated puncture opening  
in septum 310. A distal length 241 of access sheath  
240 is advanced across septum 310 into left atrium 320.  
30 After securement means 230 disposed on the distal end  
of access sheath 240 advances across septum 310,  
forward advancing motion of access sheath 240 may be  
halted. Securement means 230 may then be deployed, for  
example, by injecting pressurizing fluid through

Implant device 210 and other catheter  
15 structures including positioning guide 220 may be  
passed through delivery tube 260 into left atrium 320.  
FIG. 5 figuratively illustrates the deployment of the  
positioning guide 220 to engage atrial wall  
surfaces 430 proximate to the ostium 410 of a left  
20 atrial appendage 420 for mechanical support.

After access sheath 240 is secured against septum 310 by inflated securement means 230, and delivery tube 260 is introduced into left atrium 320, positioning tube 270 with positioning guide 220 in its compact state is advanced through delivery tube 260 into left atrium 320. Positioning tube 270 is advanced sufficiently into left atrium 320 so that positioning guide 220 butts up against or is very close ostium 410. Positioning guide 220 is then deployed so that it engages surface portions of the atrial wall 430 surrounding ostium 410. In FIG. 5, directions A figuratively depict the motion of fingers 222 during the deployment of guide 220. During the deployment fingers 222 move from a contracted configuration

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It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. It will be understood that terms like "distal" and "proximal", and other directional or orientational terms are used herein only for convenience, and that no fixed or absolute orientations are intended by the use of these terms.